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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR     | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/694,130      | 10/27/2003  | William Michael Glandorf | 6373R2RD2           | 3261             |

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CINCINNATI, OH 45224

EXAMINER

KRASS, FREDERICK F

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1614

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                       |  |  |
|------------------------------|---------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/694,130  | <b>Applicant(s)</b><br>GLANDORF ET AL. |  |
|                              | <b>Examiner</b><br>Frederick F. Krass | <b>Art Unit</b><br>1614                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2-2-04</u> . | 6) <input type="checkbox"/> Other: ____.  |

### **Claim Informalities**

The following amendments should be made to correct obvious minor informalities:

- 1) Claim 1 should be amended to end in a period.
- 2) Claim 2, first line, after "is" there should be inserted --- present ---
- 3) Claim 6, first line, the space between "stannous" and "ion" should be minimized.

### **Indefiniteness Rejection**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Claim 1, line 6, and claims 2 and claim 8, second line of each claim, in each instance the term "percent" is indefinite because the basis for its determination is not set forth, namely 1) the basis for the percentage units, e.g. percent by weight, volume, mole, etc. and 2) the basis for the overall calculation, e.g. percentage based on the total amount of the dentrifice composition, based on the amount of polyphosphate, based on the amount of the stannous ion source, etc. See Honeywell Intl., Inc. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that, where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the claimed value is indefinite unless the method of measurement is specified.)

2) Claim 1, line 7, there is no antecedent basis for the term "polyphosphate anion." Section "a" of claim 1 recites polyphosphates, not polyphosphate salts. It also recites polyphosphates which are "susceptible to hydrolysis",

i.e. which have not yet been hydrolyzed. The only way a polyphosphate anion could be present was 1) if the polyphosphate were a salt or 2) the polyphosphate were hydrolyzed and in aqueous solution. Neither possibility is recited in claim 1 so as to provide proper antecedent basis for reciting the term "polyphosphate anion".

3) Claim 10, first two lines, the recitation "aqueous carriers which are materials" is confusing, since various members of the Markush Group which follow are not what one would normally consider aqueous carriers, e.g. titanium dioxide. Since the phrase "aqueous carriers which are" is not necessary to an understanding of the claimed subject matter, the examiner recommends deleting it.

### **Obviousness Rejection**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaffar et al (USP 4,627,977) in view of Crisanti et al (USP 4,902,497).

The primary reference discloses anticalculus dentrifice compositions comprising linear polyphosphates having an average chain length of up to 125 repeating units, with hexametaphosphates (i.e., compounds having six repeating units) being preferred, in amounts ranging from 0.1 to 7.0 percent by weight. See col. 2, lines 42-56. When the dentrifice is a toothpaste, it may contain as low as 3 percent water by weight (col. 5, line 58); in lozenge or chewing gum form, it may contain no, or almost no water. (See working examples 3 and 4 at col. 9). A fluoride ion source, such as those recited by instant claim 11 (first paragraph of col. 4), and thickening agents, such as those recited by instant claim 12 (see col. 5, lines 61 et seq.), are included as well. The primary reference differs from the instant claims insofar as it does not disclose stannous ion sources other than stannous fluoride or stannous monofluorophosphate, in an amount of 0.2:1 to 5:1 stannous ion to polyphosphate anion, which do not reduce the efficacy of the stannous ions in the dentrifice. It does, however, clearly teach at the last line of col. 6 that "other anticalculus agents" may be incorporated.

The secondary reference discloses the use of stannous compounds such as stannous chloride and stannous glyconate, complexed with certain acids or alcohols, as anticalculus agents. See the passage spanning col. 1, line 64 to 3, line 25. Stannous chloride dihydrate, the preferred species of instant claim 6, may also be used. (See working example IV at the bottom of col. 5). Note that the ppm values given for stannous ions at the top of col. 3 are for a toothpaste which has been diluted with water by a factor of three. (Col. 3, lines 3 and 4). This means that the dentrifice composition contained three times those values prior to dilution, i.e. at least 3000ppm stannous ions, as required by instant claim 3. The advantage of using such complexed stannous compounds appears to reside in their improved and sustained bioavailability: see col. 2, lines 31-36. The secondary reference differs from the instant claims insofar as it is silent regarding the use of polyphosphates having an average chain length of at least four.

It would have been obvious to have used a stannous compound, such as stannous chloride dihydrate, as an additional anticalculus agent as suggested by the primary reference, motivated by the desire to provide improved and

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sustained bioavailability as taught by the secondary reference. The compositions resulting from this combination of references would thus contain from 0.1 to 7 percent by weight polyphosphate having an average chain length of at least 4, and at least 3000ppm stannous ions. Since these substantially overlap the percentages preferred by Applicant (see page 5, lines 26-30 of the specification, and also see instant claim 3), these compositions would necessarily contain the same relative proportions of polyphosphate anion to stannous ion recited instantly, i.e. between about 0.5:1 and about 3:1.

Regarding instant claim 9, the selection of the value "21" from the range disclosed by the primary reference (up to 125) would have been obvious given that value's implicit inclusion within the disclosed range. See In re Peterson, 315 F.3d 1325 (C.A. Fed. 2003). (Stating that the "normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.")

### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 10:30AM- 7PM;  
Tuesday: 10:30AM - 7PM;  
Wednesday: off;  
Thursday: 10:30AM- 7PM; and  
Friday: 10:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC)  
at 866-217-9197 (toll-free).

Frederick Krass  
Primary Examiner  
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A handwritten signature in black ink, appearing to read 'F. Krass', written over the printed name.